

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Makoto FUKUDA et al. Group Art Unit: 1777
Appln. No. : 10/553,950 Examiner: K. Zalasky
(U.S. National Stage of PCT/JP2004/005870)
I.A. Filed : April 23, 2004 Confirmation No. : 6546
For : HOLLOW FIBER MEMBRANE TYPE FLUID TREATMENT
DEVICE

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir :

I, Hirofumi MIURA, of 2-12-14, Onose, Oita-shi, Oita 870-0321, Japan, declare
as follows:

1. That I am familiar with the subject matter of U.S. Patent Application No.
10/553,950, filed October 21, 2005.
2. That I hold a Master of Engineering degree and graduated from Kyoto University
Graduates School of Engineering Department of Polymer Chemistry (in Japan) in 1997.
That I have worked for Asahi Kasei Co., Ltd since 1997, after graduating from Kyoto
University Graduates School of Engineering.

August 2, 2011 H. Hirsch

3. That I am currently employed at ~~Asahi Kasei Co., Ltd.~~ and have specific technical experience in the following technical areas:

Asahi Kasei Kuraray Medical Co., LTD.

- polymer science
- membrane separation and
- hemodialysis

4. That I have worked on developing fire resistant polymers, a leukocyte removal filter, a humidifying membrane, new hollow fibers, and new dialyzers.

5. That I am a named inventor in the following Patent Application Publications:

- JP 2000-239430, Entitled: EXPANDABLE FLAME RESISTANT PHENOLIC RESIN COMPOSITE
- WO 2003/011924, Entitled: POLYMER FOR COATING LEUKOCYTE REMOVAL FILTER MATERIAL AND THE FILTER MATERIAL
- JP 2006-192364, Entitled: VAPOR PERMEABLE MEMBRANE
- WO 2007/018284, Entitled: SEPARATION MEMBRANE FOR USE IN TREATMENT OF LIQUID COMPRISING AROMATIC ETHER POLYMER WHICH IS HYDROPHILIZED WITH HYDROPHILIZING AGENT

6. That I have reviewed the Office Action dated March 3, 2011 in the present application, in which claims 1, 13, 15, 17 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 44-5526 in view of FUKASAWA et al, wherein the Examiner states that "since the instant application is silent to unexpected results, it would have been obvious to one of ordinary skill in the art to change the lengths of the tapered and straight body portions as well as the diameters, since such a modification would have involved a mere change in size (or dimension) of a component." See page 6 of the Official Action.

7. That the presently claimed angle, formed by a centerline of the inner surface of the housing body portion and an inner surface of the end tapered portion is greater than 0° and smaller than an angle defined by $\tan^{-1}\{1/2 \cdot (d1-d4)/L4\}$ (where, d1 is the diameter of the hollow fiber membrane bundle at an end face of the resin layer, d4 is an inner diameter of the body straight portion or minimum diameter portion of the housing body portion, and L4 is the length (one side) of the end tapered portion which increases in diameter toward the end face of the housing body portion), and wherein a ratio of the length of the body straight portion to the total length of the end tapered portion is 0.7 to 20, and a ratio of the inner diameter of the end tapered portion at the end face of the housing body portion to the inner diameter of the body straight portion is more than 1 and not more than 3, is critical in providing an improved hollow fiber membrane type fluid treatment device in accordance with the present invention.

8. That the aforementioned features produce unexpected results. In particular, that the substance removal performance of the hollow fiber membrane type fluid treatment device is significantly increased, and the variation in the substance removal performance is little, and occurrence of leakage due to breakage of the hollow fiber membrane is significantly reduced depending on the diameter-expanding portion. (*See paragraph on page 33 of the present Disclosure.*)

Also, an undesirable short-path that may result from a particular taper or a tapered portion does not occur.

9. That the advantages and unexpected results are further illustrated in the attached graph which comparatively charts data corresponding to a lowest performing Example 8 *(which is illustrative of features of the applied prior art)* and the highest performing comparative Example 3 *(which is illustrative of devices in the conventional art, although not having a tapered portion)*. That the data demonstrates that *(statistically)* even the lowest performing example *(having features corresponding to the present invention)* substantially outperforms the highest performing comparative Example 3 *(as evidenced by the relatively little variation in the substance removal performance of Example 8 vs. comparative Example 3.)*

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the U.S. Code, and that such willful false statements may jeopardize the validity of the patent application or any patent issuing thereon.

Hirofumi Miura

Hirofumi MIURA

August 2, 2011

Date

Figure 1

